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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,964	11/21/2000	Michael E. O'Donnell	22221/1030 (RU-339 CIP)	2211

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08/26/2003

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EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 08/26/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/716,964

Applicant(s)

O'DONNELL ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-9,49-52,55 and 71-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,7,49-52,55 and 71-76 is/are rejected.
- 7) ☐ Claim(s) 8 and 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/28/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants amendment of the specification, cancellation of claims 2-6, 10-48, 53, 54 and 56-70 without prejudice and the amendment of claims 1, 7-9, 50, 52 and 55, and the addition of new claims 71-76, Paper No. 15, 3/21/2003, is acknowledged. Claims 1, 7-9, 49-52, 55 and 71-76 are still at issue and are present for examination. Applicants' arguments filed on 3/21/2003, Paper No. 15, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Information Disclosure Statement

Applicants filing of the information disclosure, Paper No. 17, 3/25/2003, is acknowledged. Those references initialed have been considered. It is noted that reference 1, U.S. Patent No. 5,192,674, has been lined through as it has already been considered and initialed on the previous information disclosure, Paper No. 10, 10/1/2002.

Specification

The disclosure is objected to because of the following informalities:

Applicants amendment of the specification to include the cross reference to the parent application, **09/642,218** which further recites "... all of which are hereby incorporated by reference." is objected to because incorporation by reference of the parent application, **09/642,218** is not proper. The incorporation by reference of each of

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the other applications referred to in this amendment is proper as each of these were referred to and incorporated by reference in the specification-as-filed . Applicants attention is directed to the M.P.E.P Section 201.06(c) :

Incorporation by Reference

In a continuation or divisional application, the safeguard (petition and fee under former 37 CFR 1.60(b)) concerning the filing of an application lacking all of the pages of the specification or sheets of drawings of the prior application has not been retained in 37 CFR 1.53(b) since the specification and drawings of a continuation or divisional application are not limited to a reproduction or a "true copy" of the prior application. As a safeguard, however, an applicant may incorporate by reference the prior application by including, in the continuation or divisional application-as-filed, a statement that such specifically enumerated prior application or applications are "hereby incorporated herein by reference." The statement may appear in the specification or in the application transmittal letter. The incorporation by reference statement can only be relied upon to permit the entering of a portion of the prior application into the continuation or divisional application when the portion of the prior application has been inadvertently omitted from the submitted application papers in the continuation or divisional application. The inclusion of this incorporation by reference of the prior application(s) will permit an applicant to amend the continuation or divisional application to include any subject matter in such prior application(s), without the need for a petition provided the continuation or divisional application is entitled to a filing date notwithstanding the incorporation by reference. A priority claim under 35 U.S.C. 120 in a continuation or divisional application does not amount to an incorporation by reference of the application(s) to which priority is claimed. For the incorporation by reference to be effective as a proper safeguard against the omission of a portion of a prior application, the incorporation by reference statement **must be included in the specification-as-filed, or transmittal letter-as-filed, or in an amendment specifically referred to in an oath or declaration executing the application.** Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See MPEP § 608.01(p).

Appropriate correction is required.

Claim Objections

Claims 8 and 9 are objected to because of the following informalities:

Claims 8 is dependent on rejected claim 7.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 52 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 (claim 55 dependent on) recites the limitation "the heterologous DNA molecule " according to claim 1. There is insufficient antecedent basis for this limitation in the claim. While claim 1 encompasses many DNA molecules which are heterologous to many of the host organisms, claim 1 is not directed to a heterologous DNA molecule, and hence the reference to "the" heterologous DNA molecule is improper.

Claim 73 is indefinite in that the recitation "5X sodium citrate buffer" is unclear and confusing. It is noted that applicants point to the specification page 35, lines 19-21 and page 49, lines 9-27 as descriptive support for the recited hybridization conditions, and the specification at page 30, lines 15-17 recites " 0.9 M sodium citrate ("SSC") buffer, however it remains unclear what "5X sodium citrate buffer" is and thus the metes and bounds of those molecules encompassed by claim 73 are unclear.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7 and 49-52, 55, 71-76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA molecule from a thermophilic bacterium encoding a DNA polymerase III-type enzyme delta subunit, wherein said DNA molecule comprises a nucleotide sequence of SEQ ID NO. 157, does not reasonably provide enablement for any DNA molecule from a thermophilic bacterium encoding a DNA polymerase III-type enzyme delta subunit. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was originally made in the previous office action as it applied to previous claims 1-3, 7, and 49-56. In response, applicants have cancelled claims 2, 3, 53, 54 and 56, amended claims 1, 7, 50, 52 and 55 and added new claims 71-76 and applicants traverse the rejection as it applies to the newly amended and added claims.

Applicants submit that applicants have identified the nucleotide sequence of SEQ ID NO: 157 and thus its complement and applicants have provided the hybridization conditions specified in the various claims as well as by way of example (i.e. at page 49, lines 9-27) a particular hybridization protocol. Applicants further submit that applicants have identified a procedure to determine whether a particular isolated nucleic acid

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encodes a delta subunit, by determining whether the encoded protein is capable of forming a clamp loader complex (along with a delta prime subunit and either a gamma or a tau subunit). Applicants submit that because one of ordinary skill in the art is fully capable of performing a hybridization procedure as presently claimed, the presently claimed invention specifies structural limitations and the conditions for such hybridization, and one of ordinary skill in the art is fully capable of determining whether an encoded protein is able to form a clamp loader complex with cooperating enzyme subunits, applicants have thus enabled the claimed invention.

Applicants argument is not found persuasive. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of DNA molecules broadly encompassed by the claims, including those yet to be discovered or identified. Applicants argue that the rejection under 35 U.S.C. §112, first paragraph is not proper because the specification teaches the complete nucleotide sequence of SEQ ID NO:157, and its complement, hybridization conditions and a particular hybridization protocol, and a procedure to determine whether a particular isolated nucleic acid encodes a delta subunit, by determining whether the encoded protein is capable of forming a clamp loader complex. This is not persuasive because while methods to identify and produce variants of a known sequence such as hybridization, PCR, site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as claimed by applicants (i.e., encoding a delta subunit of a DNA polymerase III-type enzyme) requires that one of ordinary skill in the art know or be provided with guidance for the selection of

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which of the infinite number of variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such **guidance** has not been provided in the instant specification. As previously stated the specification does not establish: (A) those *Thermus* species from which the claimed DNA molecules may be found, (B) regions of the protein structure which may be modified without effecting DNA polymerase III delta subunit (clamp-loading) activity; (C) the general tolerance DNA polymerase III delta subunits to modification and extent of such tolerance; (D) a rational and predictable scheme for modifying any DNA polymerase III delta subunit residues with an expectation of obtaining the desired biological function; and (E) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any DNA molecule from a thermophilic bacterium, encoding a DNA polymerase III-type enzyme delta subunit. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of

those DNA molecules having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a stylized flourish at the end.

Richard G Hutson, Ph.D.
Primary Examiner
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